3510-16-P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO-P-2021-0033]

Deferred Subject Matter Eligibility Response Pilot Program

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) is implementing a pilot program to evaluate the effects of permitting applicants to defer responding to subject matter eligibility (SME) rejections in certain patent applications. Under this pilot program, applicants may receive invitations to participate if their applications meet the criteria for the program as specified in this notice, including a criterion that the claims in the application necessitate rejections on SME and other patentability-related grounds. An applicant who accepts the invitation to participate in this pilot program must still file a reply to every Office action mailed in the application, but is permitted to defer responding to SME rejections until the earlier of final disposition of the application, or the withdrawal or obviation of all other outstanding rejections. This notice outlines the conditions, eligibility requirements, and guidelines of the pilot program.

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] to ensure consideration.

Pilot Duration: Invitations to participate in the Deferred Subject Matter Eligibility
Response (DSMER) Pilot Program will be mailed during the period beginning on February 1,
2022, and ending on July 30, 2022. The USPTO may extend the pilot program (with or without modifications) or terminate it depending on the workload and resources needed to administer the program, feedback from the public, and the effectiveness of the program. If the pilot program is extended or terminated, the USPTO will notify the public.

ADDRESSES: For reasons of Government efficiency, comments must be submitted through the Federal eRulemaking Portal at www.regulations.gov. To submit comments via the portal, enter docket number PTO-P-2021-0033 on the homepage and click "Search." The site will provide a search results page listing all documents associated with this docket. Find a reference to this notice and click on the "Comment Now!" icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in ADOBE® portable document format or MICROSOFT WORD® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal website (www.regulations.gov) for additional instructions on providing comments via the portal. If electronic submission of comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: For questions or comments regarding this pilot program in general, please contact Nalini Mummalaneni, Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patents, USPTO, at 571-270-1647. Questions regarding a specific application should be directed to the Technology Center examining the application.

SUPPLEMENTARY INFORMATION: Patent examiners at the USPTO customarily practice compact prosecution when examining patent applications. See section 2103 of the Manual of Patent Examining Procedure (MPEP, Ninth Edition, Revision 10.2019). Under the principles of compact prosecution, as described in the MPEP, an examiner reviews each claim for compliance with every requirement for patentability in the initial review of the application, and identifies all the applicable grounds of rejection in the first Office action. See MPEP 2100 for a discussion of the requirements for patentability, including the SME, utility, inventorship, and double patenting requirements of 35 U.S.C. 101; the enablement, written description, and definiteness

requirements of 35 U.S.C. 112; and the prior art-based novelty and non-obviousness requirements of 35 U.S.C. 102 and 35 U.S.C. 103, respectively. The applicant must then respond to every ground of rejection in the Office action in order to continue prosecution and avoid abandonment of the application. 37 CFR 1.111(b); MPEP 714.02.

On March 22, 2021, Senators Thom Tillis and Tom Cotton sent a letter to the Commissioner for Patents suggesting that the USPTO modify the compact prosecution process with respect to SME issues. This letter is available at https://www.uspto.gov/patents/initiatives/patent-application-initiatives/deferred-subject-matter-eligibility-response. In particular, the letter requested that the USPTO adopt a pilot program under which full prosecution of SME issues under 35 U.S.C. 101 is deferred until a patent application satisfies the other patentability conditions, and that the USPTO also determine "whether this approach is more effective, and produces higher quality patents" than the traditional compact prosecution approach.

In response to the Senators' requests, the USPTO is implementing the DSMER Pilot Program. Under this program, an applicant must still file a reply to every Office action mailed regarding a participating application, but is permitted to defer responding to SME rejections until the earlier of final disposition of the application, or the withdrawal or obviation of all other outstanding rejections. The DSMER Pilot Program thus deviates from traditional compact prosecution, because participating applicants may defer engaging with examiners on SME issues until after non-SME issues have been addressed.

This pilot program provides the USPTO with the opportunity to evaluate how deferred applicant responses to SME rejections affect examination efficiency and patent quality as compared to traditional compact prosecution practice. Because satisfaction of non-SME conditions for patentability (e.g., novelty, non-obviousness, adequacy of disclosure, and definiteness) may resolve SME issues as well, the pilot program may result in improved examination efficiency and increased patent quality as compared to compact prosecution

practice, particularly in certain technology areas.

I. Prospective Pilot Applications

The USPTO may identify an application as a prospective pilot application if it satisfies the following conditions during the invitation phase: (1) the application is assigned to a participating examiner, as explained in section I.A.; (2) the application meets the procedural criteria specified in section I.B.; and (3) the claims meet the patentability-related criteria specified in section I.C. Such identification will be made in the first Office action on the merits, which will include a form paragraph identifying the application as a prospective pilot application, inviting the applicant to participate, and informing the applicant about how to accept or decline the invitation. See section II for more information on the invitation process. The USPTO will not accept requests to have a particular application identified as a prospective pilot application.

A. Participating Examiners

This pilot program is open to primary examiners across the patent examining corps. While examiner participation is not mandatory, the USPTO will make efforts to ensure that a representative number of primary examiners are participating from each applicable Technology Center.

B. Procedural Criteria

1. Application Types

A prospective pilot application must be an original nonprovisional utility application filed under 35 U.S.C. 111(a) or an international application that has entered the national stage under 35 U.S.C. 371, and must not claim the benefit of the earlier filing date, under 35 U.S.C. 120 or 121, of any prior nonprovisional application. The application may claim the benefit of the earlier filing date, under 35 U.S.C. 120, 121, 365(c), or 386(c), of any prior international application or

international design application designating the United States, and may claim priority, under 35 U.S.C. 119, 365(a), 365(b), 386(a), or 386(b), to any prior application filed in the United States or in a foreign country, including provisional applications, international applications, and international design applications that designate at least one country other than the United States. Plant and design applications do not qualify for participation in this pilot program because they are not governed by the SME requirements of 35 U.S.C. 101.

2. Application Status

Because this pilot program is being implemented to study how applicant deferrals of responses to SME rejections affect examination efficiency, applications that have been advanced out of turn (accorded special status) do not qualify for participation in this pilot. Thus, applications that have been accorded special status under 37 CFR 1.102, or via participation in initiatives or pilot programs that advance applications out of turn and/or provide fast-track examination (e.g., the Collaborative Search Pilot Program or the COVID-19 Prioritized Examination Pilot Program), will not be invited to participate in this pilot program. Further, as a condition of entering this pilot program, an applicant must agree that they will not seek special status or expedited processing of a participating application until final disposition has been achieved in the application.

Applications participating in this pilot program may participate in initiatives that expedite processing **after** final disposition, for example, the Fast-Track Appeals Pilot Program.

Applicants of participating applications may also request prioritized examination under 37 CFR 1.102(e)(2) in connection with the filing of a request for continued examination (RCE).

Additionally, applications participating in this pilot program may take part in other USPTO initiatives or pilot programs that do not advance applications out of turn, including the After Final Consideration Pilot 2.0 (AFCP 2.0) Program, the Pre-Appeal Brief Conference Pilot

Program, and the Quick Path Information Disclosure Statement (QPIDS) Program. For more information about after-final practice, please refer to section III.C below.

C. Patentability-Related Criteria

The claims of the prospective pilot application must raise both SME issues and non-SME issues that necessitate rejections, and the first Office action on the merits must make both SME and non-SME rejections. The inclusion of SME rejections in this action will ensure that the applicant has sufficient information on which to make an educated decision about whether to participate in the pilot program. This program does not require that any individual claim be the subject of both SME and non-SME rejections. For the purposes of this pilot program, an "SME rejection" is a rejection under 35 U.S.C. 101 for lack of SME, and includes both step 1 rejections, where the claim as a whole does not fall within a statutory category, and step 2B rejections, where the claim as a whole is directed to a judicial exception without also including additional limitations amounting to significantly more than the exception. See MPEP 2106.07 for a discussion of SME rejections. Additional information about patent SME and the USPTO's evaluation of this requirement is provided in MPEP 2106 et seq., and at www.uspto.gov/PatentEligibility. A "non-SME rejection" is a rejection based on any other condition for patentability, such as, for example, utility or inventorship under 35 U.S.C. 101; enablement, written description, or definiteness under 35 U.S.C. 112; novelty under 35 U.S.C. 102; non-obviousness under 35 U.S.C. 103; or double patenting. See MPEP chapter 2100 for more information about these conditions for patentability.

II. Pilot Invitation and Election Process

A. Pilot Invitation

As explained in section I, participating examiners may invite the applicant of a prospective pilot application to participate in the pilot program by including a form paragraph in the first Office

action on the merits. The form paragraph will identify the application as a prospective pilot application, invite the applicant to participate, and inform the applicant about how to accept or decline the invitation. For purposes of issuing an invitation to participate in this program, the term "first Office action on the merits" does not include actions containing only a requirement for restriction and/or election of species. A copy of the invitation form paragraph is available on the pilot program website at https://www.uspto.gov/patents/initiatives/patent-application-initiatives/deferred-subject-matter-eligibility-response.

B. Election by the Applicant

An applicant receiving an invitation to participate in the DSMER Pilot Program may elect to accept the invitation and participate in the program or to decline participation.

If an applicant wishes to participate in the program, they must file a properly completed request form PTO/SB/456 concurrently with a timely response to the first Office action on the merits. The request form must be signed, in accordance with 37 CFR 1.33(b), by a person having the authority to prosecute the application, and must be submitted via the USPTO's patent electronic filing systems (EFS-Web or Patent Center). Use of this form will help the Office to quickly identify applications participating in this pilot program and improve the data generated on the effectiveness of the program. The form is available on the pilot program website at https://www.uspto.gov/patents/initiatives/patent-application-initiatives/deferred-subject-matter-eligibility-response. If the form is properly completed and timely received in a prospective pilot application, the application will be entered into the pilot program, and further prosecution will proceed as detailed below in section III. Form PTO/SB/456 does not collect "information" as defined in 5 CFR 1320.3(h) and therefore is exempt from the Paperwork Reduction Act of 1995.

If the applicant does not timely file a properly completed PTO/SB/456, the application will not

be entered into the program. In this case, the application will undergo the normal prosecution process as described in MPEP chapter 700, and the applicant must file a complete reply to the first Office action on the merits, as required by 37 CFR 1.111(b) and as described in MPEP 714.02.

Once an applicant has elected to participate in the pilot program, there is no provision for them to withdraw a participating application. However, applicants may, at any time, choose not to avail themselves of the program's benefit (the ability to defer responding to SME rejections in certain circumstances) and may voluntarily reply to any outstanding SME rejections. Such action does not remove the application from the pilot program or terminate the waiver for that application.

III. Pilot Procedure

A. Applicant Replies

Participation in this pilot program provides the applicant with a limited waiver of 37 CFR 1.111(b) with respect to SME rejections in the participating application, as set out below. Although the applicant must still file a reply to every Office action mailed in the participating application, the limited waiver permits the applicant to defer presenting arguments, evidence, or amendments in response to the SME rejection(s) until the earlier of final disposition of the participating application or the withdrawal or obviation of all other outstanding rejections. Other than this permitted deferral of responding to the SME rejection(s), the applicant's replies must be fully responsive to the Office action, as described in MPEP 714.02, and must be timely filed within the applicable period for reply, as extended under 37 CFR 1.136(a).

The phrase "final disposition" should be understood for a particular application as occurring upon the earliest of the: (1) mailing of a notice of allowance, (2) mailing of a final Office action, (3) filing of a notice of appeal, (4) filing of an RCE, or (5) abandonment of the application. The

phrase "withdrawal or obviation of all other outstanding rejections" refers to the situation in which a second or subsequent non-final Office action containing only the SME rejection(s) is mailed in a participating application, because the applicant has overcome, or the examiner has withdrawn, all the non-SME rejections that were previously made. Although such actions are not final dispositions, they are effective in terminating the limited waiver of 37 CFR 1.111(b) for that participating application. This termination is necessary because the applicant is required by 35 U.S.C. 132 and 133 to respond to Office actions in order to prevent abandonment of the application.

Prior to termination of the waiver (whether by final disposition or by the withdrawal or obviation of all other outstanding rejections), the applicant may defer responding to any particular SME rejection in a participating application. For example, if the applicant accepts the invitation to participate in the pilot program, in compliance with section II.B above, for an application having a first Office action on the merits setting forth a step 1 SME rejection, a step 2B SME rejection, and an anticipation rejection, an applicant may exercise any of the following options when filing a reply to the action:

- Respond only to the anticipation rejection and remain silent on the SME rejections, pursuant to the limited waiver of 37 CFR 1.111(b);
- Respond to the anticipation rejection and one of the SME rejections, and remain silent on the other SME rejection, pursuant to the limited waiver of 37 CFR 1.111(b); or
- Respond to all three rejections.

Any of these three replies will be considered as an adequate reply to the SME rejection(s) for purposes of evaluating whether the applicant has made a *bona fide* attempt to advance the application to final action.

Upon final disposition, or the withdrawal or obviation of all other outstanding rejections (which

would normally occur in a final Office action but may, in some circumstances, occur in a second or subsequent non-final Office action), the limited waiver of 37 CFR 1.111(b) provided by this pilot program ends, and the applicant may no longer defer responding to any outstanding SME rejection(s). See section III.C below for more information on after-final practice.

In the event that circumstances require the USPTO to remove an application from this pilot program, the limited waiver of 37 CFR 1.111(b) ends, and the applicant may no longer defer responding to any outstanding SME rejection(s). Such circumstances may occur, for instance, if the application must be transferred upon the retirement of the original examiner. In the event of removal, the applicant will be notified that the application no longer qualifies for the pilot program.

B. Examiner Actions

An examiner's or applicant's participation in this pilot program does not alter the normal prosecution process, as described in MPEP chapter 700, except for the SME response deferral outlined above in section III.A. Thus, for example, interviews conducted in participating applications must be made of record, in accordance with the normal interview procedure (see MPEP 713), and the written statement of the substance of the interview must capture all matters discussed (including any SME rejection-related discussions) between the applicant and the examiner, in accordance with normal interview practice (see MPEP 713.04).

Even though the limited waiver of 37 CFR 1.111(b) permits the applicant to defer responding to an SME rejection, the examiner will consider whether the applicant's responses to other rejections (e.g., amendments made in response to an obviousness or indefiniteness rejection) overcome the SME rejection(s) of record. In cases where the applicant's reply overcomes all outstanding rejections, including the SME rejection(s) set forth in the Office action, and the

application is otherwise in condition for allowance, the examiner will issue a Notice of Allowance. If the examiner believes that the record of the prosecution as a whole does not make clear their reasons for allowing a claim or claims, the examiner may set forth such reasoning in the Notice of Allowance, as described in MPEP 1302.14. Issuance of a Notice of Allowance is a final disposition that concludes the limited waiver of 37 CFR 1.111(b) for that particular application.

In cases where the applicant's reply does not overcome all outstanding rejections, the examiner will issue a subsequent Office action setting forth all applicable rejections, including any applicable SME rejection(s), and addressing all amendments, arguments, and evidence provided by the applicant. In accordance with normal prosecution practice and as explained in MPEP 706.07(a), the subsequent action will typically be a final action, except in limited circumstances. Issuance of a final rejection is a final disposition that concludes the limited waiver of 37 CFR 1.111(b) for that particular application. If the subsequent Office action is a non-final action, and a non-SME rejection(s) remains outstanding, the applicant may continue deferring their response to any outstanding SME rejection(s) set forth in the subsequent Office action, as described above in section III.A. If the subsequent Office action is a non-final action, and there are no non-SME rejections outstanding, the limited waiver is terminated, and the applicant must respond to the outstanding SME rejection(s), as described above in section III.A.

C. After-Final and Appeal Practice

As stated earlier, a final disposition of the application ends the limited waiver of 37 CFR 1.111(b) provided by this pilot program. Thus, the applicant may not defer responding to any outstanding SME rejection(s) after final disposition (e.g., after the mailing of a final Office action, filing of a notice of appeal, or filing of an RCE). If the applicant chooses to file an after-final response, it must be complete, in accordance with 37 CFR 1.111(b), and any amendment,

affidavit, or other evidence submitted after a final Office action and prior to appeal must comply with 37 CFR 1.116. If the applicant chooses to file a Notice of Appeal, the application will be treated in accordance with the normal appeal procedure (see MPEP chapter 1200), and the applicant must present arguments with respect to each ground of rejection (including SME rejections) that is contested, pursuant to 37 CFR 41.37(c)(1)(iv). Applicants are cautioned that participation in this program is not, in itself, a good and sufficient reason why an amendment or evidence was not earlier presented under 37 CFR 1.116 or 41.33. See, e.g., MPEP 714.12 and MPEP 1206 regarding amendments and other replies after final rejection or appeal.

If the applicant chooses to file an RCE, they must submit a complete response to the final Office action, including a response to any outstanding SME rejection(s), with the RCE as required by normal rules of practice.

Because abandonment is a final disposition, it also ends the limited waiver of 37 CFR 1.111(b) provided by this pilot program. Thus, if a participating application is abandoned, the applicant may not defer responding to any outstanding SME rejection(s) if the application is later revived, even if the application was abandoned due to failure to respond to a non-final Office action. Accordingly, a grantable petition for revival of a participating application that is abandoned must be accompanied by a complete reply to any outstanding SME rejection(s) of record, in addition to the other requirements of such petitions under 37 CFR 1.137 and Office practice. Due to this particular response requirement, a petition for revival of a participating application may not be filed as an e-Petition and instead must be filed by: (1) uploading the petition and accompanying papers using a USPTO electronic filing system (EFS-Web or Patent Center); (2) physical delivery to the USPTO by way of the United States Postal Service, another delivery service, or by hand delivery to the USPTO Customer Service Window; or (3) facsimile. More information about these delivery options is available at www.uspto.gov/patents/apply/petitions/02-where-file-

petitions-requests-and-related-inquiries-office.

An application participating in this pilot program may participate in other USPTO initiatives

after final disposition of the application if it satisfies the conditions of those other initiatives.

Such initiatives include, for example, the AFCP 2.0 Program, the Fast-Track Appeals Pilot

Program, the Fast-Track for COVID-19-Related Appeals Pilot Program, the Pre-Appeal Brief

Conference Pilot Program, and the QPIDS Program. An application participating in this pilot

program may also request special status or expedited processing in connection with the filing of

an RCE (e.g., prioritized examination under 37 CFR 1.102(e)(2)).

Andrew Hirshfeld,

Commissioner for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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